

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY)	MDL No.1456
AVERAGE WHOLESALE PRICE)	
LITIGATION)	Master File No. 01-CV-12257-PBS
)	Subcategory Case No. 06-11337-PBS
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THIS DOCUMENT RELATES TO:)	Judge Patti B. Saris
<i>United States of America ex rel. Ven-A-Care of</i>)	
<i>the Florida Keys, Inc., et al. v. Boehringer</i>)	Magistrate Judge Marianne B. Bowler
<i>Ingelheim Corporation, et al., Civil Action No.</i>)	
07-10248-PBS)	

**DEFENDANTS BOEHRINGER INGELHEIM CORPORATION'S AND BOEHRINGER
INGELHEIM PHARMACEUTICAL INC.'S MEMORANDUM IN SUPPORT
OF THEIR MOTION FOR SUMMARY JUDGMENT**

TABLE OF CONTENTS

INTRODUCTION	1
I. THE UNDISPUTED FACTS WARRANT SUMMARY JUDGMENT IN FAVOR OF BIC AND BIPI.....	2
A. BIC, BIPI and Roxane are Separately Incorporated Entities that Each Served a Distinct Business Purpose.....	2
B. Roxane Respected All Corporate Formalities and Maintained Independent Financial Records and Sufficient Capitalization.....	3
C. Roxane Controlled its Day-To-Day Business Operations, Including the Pricing and Marketing of its Products.	4
1. Roxane Priced and Marketed its Multisource Products.....	4
2. Roxane Priced and Marketed its Brand and Branded Generic Products.....	6
D. The Interactions Between Roxane, BIPI and BIC were Appropriate and Typical Among Parents, Subsidiaries and Affiliate Companies.....	7
ARGUMENT	8
II. BIC AND BIPI ARE ENTITLED TO SUMMARY JUDGMENT ON PLAINTIFFS' ALTER EGO CLAIM.....	8
A. The Law Disfavors Alter Ego Claims and Imposes a High Evidentiary Burden Before Allowing Plaintiffs To Pierce a Corporate Veil.....	8
B. Roxane Operated Independently from BIC and BIPI.....	9
C. Neither BIC Nor BIPI Intended to Use Roxane's Corporate Form as a Fraud.	12
III. THERE IS NO VIABLE DIRECT LIABILITY CLAIM AGAINST BIC OR BIPI.....	14
A. Plaintiffs' FCA Claims Fail As A Matter Of Law Because There Is No Evidence Showing Causation or Knowledge.....	14
B. Neither BIC Nor BIPI Took Action To Cause False Claims To Be Submitted Or False Records To Be Created.	16
1. There is no evidence that BIC had any involvement in setting or reporting AWPs for Roxane products.....	16

2.	There is no evidence that BIPI had any involvement in setting or reporting AWPs for Roxane's generic drugs.....	17
3.	Plaintiffs' "evidence" with respect to Roxane's few branded generic drugs is insufficient to establish direct liability for BIPI.....	17
	CONCLUSION.....	20

TABLE OF AUTHORITIES

Cases

<i>Allison Engine Co., v. U.S. ex rel. Sanders,</i> 128 S. Ct. 2123 (U.S. 2008).....	15
<i>Am. Med. Sys., Inc. v. Biolitec, Inc.,</i> 604 F.Supp. 2d 325 (D. Mass. 2009).....	10, 19
<i>Barbour v. Dynamics Research Corp.,</i> 63 F.3d 32 (1st Cir. 1995).....	8
<i>Bogdahn v. Hamilton Standard,</i> 973 F.Supp. 52 (D. Mass. 1997)	14
<i>Commonwealth Aluminum Corp. v. Baldwin Corp.,</i> 980 F. Supp. 598 (D. Mass. 1997)	8
<i>Dickson Marine, Inc. v. Panalpina, Inc.,</i> 179 F.3d 331 (5th Cir. 1999)	18
<i>George Hyman Constr. Co. v. Gateman,</i> 16 F. Supp. 2d 129 (D. Mass. 1998)	8, 10
<i>In re Acushnet River,</i> 675 F. Supp. 22 (D. Mass. 1987)	8, 10, 11
<i>In re Lupron Marketing & Sales Practices Litig.,</i> 245 F. Supp. 2d 280 (D. Mass. 2003)	10
<i>In re Pharm. Indus. Average Wholesale Price Litig.,</i> 478 F. Supp. 2d 164 (D. Mass. 2007)	16
<i>In re Pharm. Indus. Average Wholesale Price Litig.,</i> 491 F. Supp. 2d 12 (D. Mass. 2007)	16
<i>Intergen N.V. v. Grina,</i> 344 F.3d 134 (1st Cir. 2003).....	10
<i>Logiodice v. Trustees of Me. Cent. Inst.,</i> 170 F. Supp. 2d 16 (D. Me. 2001)	14
<i>Logiodice v. Trustees of Me. Cent. Inst.,</i> 296 F.3d 22 (1st Cir. 2002).....	14
<i>Mass. v. Mylan Labs., et al.,</i> 608 F.Supp. 2d 127 (D. Mass. 2008)	16

<i>Nichols v. Pabtex, Inc.,</i> 151 F. Supp.2d 772 (E.D. Texas 2001).....	18
<i>U.S. ex rel. Bartlett v. Tyrone Hosp., Inc.,</i> 234 F.R.D. 113 (W.D. Pa. 2006)	15
<i>U.S. ex rel. Gagne v. City of Worcester,</i> 565 F.3d 40 (D. Mass. 2009)	15
<i>U.S. ex rel. Kneepkins v. Gambro Healthcare, Inc.,</i> 115 F. Supp. 2d 35 (D. Mass. 2000)	9, 12, 14
<i>U.S. ex rel. Siewick v. Jamieson Science and Eng'g,</i> 191 F. Supp. 2d 17 (D.D.C. 2002).....	13, 14
<i>U.S. ex rel. Siewick v. Jamieson Science and Eng'g,</i> 322 F.3d 738 (D.C. Cir. 2003).....	13
<i>U.S. ex rel. Tillson v. Lockheed Martin Energy Sys.,</i> No. 5:00CV-39-M, 5:99CV-170-M, 2004 WL 2403114, *33 (W.D. Ky. Sept. 30, 2004)	15
<i>U.S. v. Bestfoods,</i> 524 U.S. 51 (1998).....	passim
<i>U.S. v. Kimbell Foods, Inc.,</i> 440 U.S. 715 (1979).....	9
<i>U.S. v. Mountzoures,</i> 376 F. Supp. 2d 13 (D. Mass. 2005)	9
<i>U.S. v. Pres. & Fellows of Harvard College,</i> 323 F. Supp. 2d 151 (D. Mass. 2004)	15
<i>United Elec., Radio, and Mach. Workers of Am. v. 163 Pleasant St. Corp.,</i> 960 F.2d 1080 (1st Cir. 1992).....	passim

INTRODUCTION

The nine subject drugs in this case are *Roxane* drugs. *Roxane* determined the AWPs and WACs for those drugs and reported them to the third party pricing compendia. *Roxane* was responsible for marketing and selling the drugs. Indeed, Plaintiffs' own Complaint focuses on *Roxane's* alleged false reporting of prices for *Roxane* drugs and *Roxane's* alleged efforts to market the spread. Ignoring these undisputed facts, Plaintiffs named *Roxane*'s parent holding company, Boehringer Ingelheim Corporation ("BIC"), and its sister company, Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI"), as defendants, alleging vague claims of alter ego liability. With discovery now closed, however, there is insufficient evidence in the record to justify piercing *Roxane*'s corporate veil, and Plaintiffs' impermissible attempt to find a "deeper pocket" to fund their outsized damages claims should be rejected by this Court.

The Government cannot meet its high evidentiary burden to establish the disfavored remedy of piercing a corporate veil. *Roxane*, which specializes in marketing and selling generic drugs, is in a very different line of business from BIC, which has never manufactured, marketed, or sold any drugs, and from BIPI, which focuses on marketing brand-name, patent-protected drugs, none of which is at issue in this case. The undisputed facts show that *Roxane* conducted its business independently and according to best corporate practices, maintaining all corporate formalities, separate financial records, sufficient capitalization and control of its day to day business activities. There is no evidence that *Roxane* was formed or operated for a fraudulent purpose. Moreover, the facts, as well as the uncontroverted expert testimony of Defendants' corporate governance expert, Professor Jonathan Macey, confirm that the interactions between *Roxane*, BIC and BIPI were appropriate and typical among related – but separate – companies. Indeed, if the corporate veil were pierced in this case, it would set a precedent that could

jeopardize the bedrock principle of limited liability for many corporations throughout the United States.

Confronted by the reality that its unsubstantiated alter ego claim is meritless, the Government recently asserted a newfound theory of liability against BIC and BIPI, claiming that they now should be held *directly liable* under the Federal False Claims Act for their alleged direct involvement in Roxane's purported fraud. Setting aside that this theory is noticeably absent from the Complaint and should not be entertained at this late date, there is no evidence that BIC or BIPI took any action that caused false claims for Roxane's drugs to be submitted to the government. Rather, the undisputed facts preclude liability for either BIC or BIPI under any legal theory. Accordingly, this Court should grant summary judgment in favor of BIC and BIPI.

I. THE UNDISPUTED FACTS WARRANT SUMMARY JUDGMENT IN FAVOR OF BIC AND BIPI.

A. BIC, BIPI and Roxane are Separately Incorporated Entities that Each Served a Distinct Business Purpose.

While BIC, BIPI, and Roxane are all part of the family-owned Boehringer Ingelheim corporate group, the companies are, and always have been, separately incorporated legal entities that each has its own corporate history and distinct business purpose:

- BIC, a Nevada company, is largely a parent holding company for Roxane, BIPI and several other U.S. subsidiaries and is located in Ridgefield, Connecticut. (56.1 ¶¶ 1-2, 5, 13) BIC has never manufactured, marketed, or sold any pharmaceutical products and has no active business of its own. (56.1 ¶ 3)
- BIPI, a Delaware corporation, is also located in Ridgefield, Connecticut. (56.1 ¶ 5) BIPI is in the business of marketing and selling brand-name, patent-protected pharmaceutical products, which carry a BIPI label and are assigned BIPI's FDA labeler code, 00597. (56.1 ¶¶ 5-6) BIPI has its own customers and a large physician sales force promotes its products. (56.1 ¶¶ 8-9, 20)

- Roxane, a Delaware corporation during the relevant timeframe, is headquartered in Columbus, Ohio.¹ (56.1 ¶ 11) Roxane was incorporated and operated as a stand-alone pharmaceutical company long before it was acquired by the Boehringer group of companies in 1978. (56.1 ¶ 10) Multisource products have always been the primary focus of Roxane's sales and marketing business. Until 2001, Roxane also marketed a small line of specialty palliative care brand and branded generic products.² (56.1 ¶¶ 16, 72) In September 2001, those products were either divested to Elan Pharmaceuticals or transferred back to BIPI, which had originally licensed them to Roxane. (56.1 ¶¶ 80-82) Since then, Roxane has almost exclusively marketed generic, multisource products.

B. Roxane Respected All Corporate Formalities and Maintained Independent Financial Records and Sufficient Capitalization.

Roxane has always maintained corporate formalities consistent with its status as a separate corporate entity. Roxane had its own, fully-functioning board of directors. (56.1 ¶¶ 21-29) In accordance with its bylaws and Delaware law, Roxane's Board acted through unanimous written consents and conducted all appropriate board actions. (56.1 ¶¶ 22, 23-29) The board appointed officers, approved financial reports and budgets, and approved significant corporate actions. (56.1 ¶¶ 23-29)

Roxane kept separate financial records and created individual financial statements. (56.1 ¶ 31) A separate entity within the BIC corporate group, BI Services Center, Inc. ("BISC") provided centralized financial and cash management services for Roxane and its affiliates. (56.1 ¶¶ 32-33) At the end of each day, the funds in each subsidiary's separate lock box account were

¹ In April 2005, Roxane was restructured and divided into two legal entities. The original Roxane Laboratories, Inc., was re-named Boehringer Ingelheim Roxane, Inc. ("BIRI") and retained the manufacturing and distribution functions of the former Roxane. A new Nevada corporation was simultaneously formed and was called Roxane Laboratories, Inc. ("RLI"). The new Roxane conducts the marketing and sales functions. (56.1 ¶ 12) Both RLI and BIRI are named as defendants here. However, because only the sales and marketing functions are at issue, BIRI is not relevant to this motion. To the extent the relevant timeframe of this case extends beyond 2005, Roxane is used to refer collectively to the Delaware company called Roxane Labs prior to 2005 and the Nevada corporation called Roxane Labs post-2005.

² Branded generics in the context of Roxane's business are generic drugs that have been given a proprietary name and were marketed to physicians similar to brands. These products were generally given an identifiable Roxane product name beyond the chemical formulation, such as Roxicodone. (56.1 ¶ 73) Three of the branded generics products divested to Elan in 2001 are at issue here: Roxicodone, Roxanol, Oramorph SR. See First Amended Compl. at ¶ 58.

swept into a master account for investment purposes. Each subsidiary's separate deposits and withdrawals were tracked and recorded. (56.1 ¶ 33)

Roxane was sufficiently capitalized at all times. Roxane consistently generated income and maintained substantial retained earnings. (56.1 ¶¶ 36-40, 95) Roxane's board of directors authorized dividend payments to BIC based on the amount of its retained earnings and income. After accounting for dividend payments, Roxane continued to maintain capital levels sufficient for its type of business. (56.1 ¶¶ 38-39)

C. Roxane Controlled its Day-To-Day Business Operations, Including the Pricing and Marketing of its Products.

The undisputed facts demonstrate that Roxane operated as an independent company:

- Roxane had its own offices and headquarters in a different city and state from its parent and affiliates. (56.1 ¶¶ 1, 5, 11)
- Roxane hired and fired its own employees and provided separate benefit plans. (56.1 ¶ 14)
- Roxane held substantial assets in its name, including its plant and equipment and rights, title and interest in many products. (56.1 ¶ 40)
- Roxane had name recognition in the marketplace with an entire line of Roxane-labeled products. (56.1 ¶ 15)
- Roxane sold its products to its own customers with whom it negotiated and entered into contracts. (56.1 ¶ 17)
- As described in greater detail below, Roxane had its own marketing department and sales force staffed by Roxane employees. (56.1 ¶ 52-53, 75-77)

1. Roxane Priced and Marketed its Multisource Products.

Six of the nine Roxane products at issue in this case are multisource drugs, and the overwhelming majority of the claims at issue are tied to these generic products, with one drug in particular, ipratropium bromide, accounting for over 75% of the Government's damages figure. The undisputed facts demonstrate that Roxane's marketing department, including specific

employees Judy Waterer and Lesli Paoletti, were responsible for determining marketing strategy, launch plans, and pricing of Roxane's generic products. That role included setting WACs and AWPs at the time a product was launched. (56.1 ¶¶ 52-54) Employees in Roxane's marketing or trade relations group were then responsible for providing and verifying WACs and AWPs to the publishing compendia. (56.1 ¶¶ 63-64) Roxane's marketing group in coordination with the contracts department established the range of contract prices that could be offered to customers. (56.1 ¶ 54) Initial launch prices and price changes were generally circulated to a group of Roxane employees for information and sign-off purposes. (56.1 ¶¶ 55, 61) Price approvals for multisource drugs never went to any pricing committee other than the Roxane employees who received the circulated price form. (56.1 ¶¶ 55) Roxane had National Account Managers ("NAMs"), who handled day-to-day marketing and sales interactions with customers for Roxane's generic products. (56.1 ¶ 65)

Until late 1998, Roxane's multisource marketing department reported to Ed Tupa, Vice-President of Marketing at Roxane. (56.1 ¶ 56) When Tupa left the company in October 1998, Tom Russillo, who was the President of another BIC subsidiary, Ben Venue Laboratories, Inc. (BVL), took on the additional position of Head of Multisource Marketing for Roxane. (56.1 ¶ 57) The multisource marketing department then reported to him, and he "ultimately managed" the pricing process for Roxane's multisource drugs. (56.1 ¶¶ 58, 60) As before, pricing recommendations were routed to various Roxane employees for information and sign-off purposes. (56.1 ¶ 61) Mr. Russillo generally did not seek further approval from his superiors regarding Roxane's multisource prices. To the extent he did, he discussed issues with Werner Gerstenberg, who was the President of Roxane. (56.1 ¶¶ 30, 62) Although Mr. Gerstenberg was

also the President of BIC, Mr. Russillo discussed Roxane pricing issues with Gerstenberg as the President of Roxane. (56.1 ¶¶ 62, 71)

2. Roxane Priced and Marketed its Brand and Branded Generic Products.

Only three of the drugs at issue in this case, Roxicodone, Oramorph SR and Roxanol, were part of the small brand and branded generic group of palliative care and HIV products that Roxane marketed until 2001. (56.1 ¶¶ 72, 80-81) While many of the drugs in this line faced generic competition, Roxane gave them proprietary names and marketed them to physicians. (56.1 ¶ 74) Roxane had its own sales force calling on physicians to sell these products and a marketing staff dedicated to promoting these products separate from the multisource team. (56.1 ¶¶ 75, 77) This Roxane staff, along with their manager, Ed Tupa, Vice President of Marketing at Roxane, developed the prices for Roxane's branded generic products. (*Id.*) Following Mr. Tupa's departure in late 1998, organizational changes allowed Roxane to leverage the expertise and experience in marketing brand name products of several BIPI employees for the benefit of Roxane's brand and branded generic products. (56.1 ¶ 78) These BIPI employees were given high-level titles and oversight responsibilities for the marketing and sales of Roxane's brand and branded generic products. (56.1 ¶¶ 78-79) Roxane employees, however, continued to handle the day-to-day sales and marketing operations of its palliative care line. (56.1 ¶ 79) Once these drugs were divested in 2001, Roxane marketed almost exclusively generic drugs and BIPI employees no longer had any role in Roxane's marketing and sales. (56.1 ¶¶ 81-82)

D. The Interactions Between Roxane, BIPI and BIC were Appropriate and Typical Among Parents, Subsidiaries and Affiliate Companies.

As a wholly-owned subsidiary and affiliate in a larger corporate family, Roxane did engage in certain typical and appropriate inter-company transactions with affiliates, all conducted at arms-length. For example, for certain periods, Roxane manufactured various products for BIPI. (56.1 ¶¶ 41-43) Written contracts governed the manufacturing transactions and specified all terms and conditions, including the price. The profit margin Roxane received was validated by outside independent consultants as a reasonable rate. (56.1 ¶¶ 42-44) Similarly, BIPI licensed certain products to Roxane, and, in exchange, Roxane paid BIPI a royalty rate, which was also validated by third party consultants. (56.1 ¶¶ 45-48)

As is common among U.S. corporate groups, a number of centralized or shared services were provided by various departments within BIPI for multiple subsidiaries. (56.1 ¶¶ 49, 89) For example, the legal, IT, contracts administration and tax departments within BIPI provided services to Roxane and other BIC subsidiaries. (56.1 ¶ 49) Roxane's use of these services was tracked, accounted for and separately paid for by Roxane. (56.1 ¶¶ 49-50).

As is also typical of affiliated corporations, BIC and its subsidiaries made efforts at times to take advantage of certain natural synergies and efficiencies that could be gained by high level coordination of overlapping areas of business. (56.1 ¶ 51) For example, for a period of time before Roxane divested its few brand products, a business unit concept was put in place to coordinate high level strategic oversight of BIPI and Roxane's common business areas. Sheldon Berkle, a BIPI employee and Roxane board member, was designated as Vice-President of the Business Unit. (56.1 ¶ 51) Although Roxane was part of the same strategic business unit as BIPI, it is undisputed that it remained a distinct legal entity and, as discussed above, operated day-to-day as a separate business.

ARGUMENT

Given the undisputed facts in this case, there is no legal theory under which the Government can hold either BIC or BIPI liable for violations of the FCA or unjust enrichment. *See Barbour v. Dynamics Research Corp.*, 63 F.3d 32, 36-37 (1st Cir. 1995) (setting forth summary judgment standard). Neither BIC nor BIPI can be held liable for claims based solely on their mere status as Roxane's parent or sister corporation. Thus, the Government must come forward with sufficient evidence to show that BIC and BIPI were "alter egos" of Roxane, or that BIC and BIPI — by their own actions — caused the submission to the government of false claims for reimbursement of Roxane drugs. No such evidence exists.

II. BIC AND BIPI ARE ENTITLED TO SUMMARY JUDGMENT ON PLAINTIFFS' ALTER EGO CLAIM.

A. The Law Disfavors Alter Ego Claims and Imposes a High Evidentiary Burden Before Allowing Plaintiffs To Pierce a Corporate Veil.

"[I]t is a general principle of corporate law deeply ingrained in our economic and legal system that a parent corporation ... is not liable for the acts of its subsidiaries." *U.S. v. Bestfoods*, 524 U.S. 51, 61 (1998) (internal quotations omitted). The presumption of limited liability encourages investment and corporate diversification because it limits the extent of the investor's risk. *See In re Acushnet River*, 675 F. Supp. 22, 32 (D. Mass. 1987). Thus, the law strongly disfavors disregarding the corporate form in order to impose liability for the acts of one corporation on another and imposes a high burden on plaintiffs seeking to pierce a corporate veil. *See George Hyman Constr. Co. v. Gateman*, 16 F. Supp. 2d 129, 157 (D. Mass. 1998) (noting that "[b]ecause piercing 'is the exception, not the rule,' . . . plaintiffs 'must meet a very high standard' before they will be allowed to disregard a corporate form") (quoting *Commonwealth Aluminum Corp. v. Baldwin Corp.*, 980 F. Supp. 598, 605 (D. Mass. 1997); *United Elec., Radio, and Mach. Workers of Am. v. 163 Pleasant St. Corp.*, 960 F.2d 1080, 1093 (1st Cir. 1992) (courts

set intent and inequity requirements because “[a] more free-wheeling approach to veil-piercing would hamstring established businesses in their legitimate efforts to expand into new fields; undermine the predictability of corporate risk-taking; and provide a huge disincentive for the investment of venture capital.”)

In the First Circuit, courts will pierce the corporate veil if, and only if, *three* conditions are met: (1) the parent and subsidiary ignored the independence of their separate operations, (2) the principal had fraudulent intent, and (3) failure to pierce the corporate veil would result in substantial injustice to the proponent of veil piercing. *See U.S. v. Mountzoures*, 376 F. Supp. 2d 13, 18 (D. Mass. 2005) (granting summary judgment where corporate formalities were observed and there was no evidence of fraudulent intent).³ While failure to prove any one of these three requirements is fatal to the Government’s claim, in this case, the evidence fails as to all three.

B. Roxane Operated Independently from BIC and BIPI.

Courts in the First Circuit look to a number of factors to determine whether the first condition, lack of independent operations, has been met, including:

- (1) whether a corporation is operated as a separate entity;
- (2) commingling of funds and other assets;
- (3) failure to maintain adequate records or minutes;
- (4) the nature of the corporation’s ownership and control;
- (5) absence of corporate assets and undercapitalization;
- (6) use of the corporation as a mere shell, instrumentality or conduit of an individual or another corporation;
- (7) disregard of legal formalities and the failure to maintain an arms-length relationship among related entities; and
- (8) diversion of the corporation’s funds or assets to noncorporate uses.

³ Because Plaintiffs’ claims arise under a federal statute, federal law controls the veil-piercing question. *U.S. ex rel. Kneepkins v. Gambio Healthcare, Inc.*, 115 F. Supp. 2d 35, 39 (D. Mass. 2000) (applying federal common law to veil-piercing determination for False Claims Act and Medicare claims) (citing *U.S. v. Kimbell Foods, Inc.*, 440 U.S. 715, 726 (1979)).

Intergen N.V. v. Grina, 344 F.3d 134, 149 (1st Cir. 2003). No individual factor is determinative; rather they are used as benchmarks for measuring typical parent-subsidiary behavior. Recognizing that some level of integration and control is inherent in every affiliate relationship, courts will not disregard the corporate form unless the interactions are well outside of the norm. See, e.g., *In re Acushnet River*, 675 F. Supp. at 35 (“[t]o the extent that Aerovox is integrated into or controlled by RTE, the relationship does not appear to be at a level uncommon between parent and wholly owned subsidiary”); *In re Lupron Marketing & Sales Practices Litig.*, 245 F. Supp. 2d 280, 292 (D. Mass. 2003) (“[t]he bulk of plaintiffs’ alter-ego theory is based on the customary incidents of a parent-subsidiary relationship – ownership, common personnel, profits, and managerial oversight …[t]hese emblems are not suspect”); *Am. Med. Sys., Inc. v. Biolitec, Inc.*, 604 F.Supp. 2d 325, 329 (D. Mass. 2009) (“none of this evidence indicates that [the defendants] enjoyed anything other than the traditional parent-subsidiary relationship established for purpose of limiting the parent’s liabilities and obligations”).

As the factors listed above demonstrate, a key component of the alter ego analysis is whether the corporation in question is a legitimate, profit-seeking entity, or merely an empty “shell” or “instrumentality” of the parent. A legitimate subsidiary is well-capitalized, can generate wealth independently, pays dividends to shareholders, observes corporate formalities, and maintains corporate records. See *George Hyman Constr. Co.*, 16 F. Supp. 2d at 153-154; see also *163 Pleasant St. Corp.*, 960 F.2d at 1093-94. Corporate legitimacy is not threatened by a mere overlap in directors, officers, or management. *Bestfoods*, 524 U.S. at 68-69. Indeed, it is entirely appropriate for a parent and subsidiary to have common management and overlapping, or even identical, directors. *Id.*

The undisputed facts here, as well as the uncontested testimony of Professor Macey, demonstrate that Roxane operated as a separate, independent company from both BIC and BIPI.⁴ (56.1 ¶¶ 86, 95-96) As discussed in detail above, Roxane was a profit-generating, sufficiently capitalized business that maintained all corporate formalities and separate finances. There is no evidence (or even allegation) of inappropriate commingling or diversion of Roxane's funds or assets. Roxane operated its day-to-day business and its marketing and sales departments independently. The relationships and interactions Roxane did have with BIC and BIPI were appropriate, conducted at arms-length and well within the norm for ordinary affiliate companies. *See e.g., In re Acushnet*, 675 F. Supp. at 34 (centralized cash management system, informal intercompany loans, and use of parent's accounting procedures are standard in parent-subsidiary relationship); *163 Pleasant St.*, 960 F.2d at 1083-84 (ordinary relationship where parent and subsidiary had overlapping directors and officers and subsidiary provided monthly financial reports to parent); *see also* Macey Testimony (56.1 ¶¶ 85-90)). Under these facts, no reasonable juror could conclude that Roxane was merely a shell or instrumentality of BIC or BIPI.

Nor does the fact that a few BIPI employees took on short-lived and strategic oversight positions for the marketing and sales of Roxane's brand and branded generic products alter the outcome. First, as will be discussed more below, the BIPI employees that served in these roles wore "Roxane hats" and acted on behalf of, and for the benefit of Roxane and, therefore, their conduct cannot be imputed to BIPI. *Bestfoods*, 524 U.S. at 68-70. Moreover, even if acting on behalf of BIPI, in light of the overall record of corporate separateness among these companies

⁴ Professor Jonathan Macey is the Deputy Dean and Sam Harris Professor of Corporate Law, Corporate Finance and Securities Law at the Yale Law School and Professor in the Yale School of Management. He is an expert in corporate governance and organization, having studied, taught and written extensively on the topics. The Plaintiffs have not proffered a corporate governance expert, and therefore Professor Macey's expert testimony that Roxane complied with all corporate formalities and that the interactions and relationships between Roxane, BIC and BIPI were common and typical among affiliated companies is uncontested. (56.1 ¶ 83-86)

and the breadth of Roxane's business, the high-level involvement by a few employees of a sister company with no ownership interest in Roxane in a narrow area of business and for a limited time period does not come close to the level of pervasive control necessary to justify piercing Roxane's corporate veil. *Bestfoods*, 524 U.S. at 64, n.10. On the contrary, the fact that BIPI personnel held overlapping management roles at Roxane and BIPI and provided high level marketing supervision is nothing out of the ordinary for affiliate companies. *See Am. Med. Sys. v. Biolitec, Inc.*, 604 F.Supp. 2d 325, 329 (D. Mass 2009) (holding that allegation that parent oversees and controls subsidiaries and works jointly to market their products is nothing other than "traditional parent-subsidiary relationship"); *In re Lupron Mkt. and Sales Prac. Litig.*, 245 F. Supp. 2d, 280, 291-292 (D. Mass. 2003) (holding that ultimate authority of parent to approve subsidiary's marketing strategies or business plans is insufficient to show parental control); 56.1¶ 90 (Professor Macey explains that it is "beyond routine" for affiliate employees to lend their management expertise and experience to and for the benefit of a sister corporation).

C. Neither BIC Nor BIPI Intended to Use Roxane's Corporate Form as a Fraud.

Even if a subsidiary lacks independence from its parent, courts will not disregard the corporate form absent evidence that the parent had fraudulent intent, namely that it "maintained the subsidiary to avoid its statutory responsibilities, acted in a blameworthy manner, looted the subsidiary, or so undercapitalized the subsidiary that the latter could not reasonably have been expected to meet its obligations." *163 Pleasant St.*, 960 F.2d at 1093. This finding of fraudulent intent "is a *sine qua non* to the [alter ego] remedy's availability." *Id.*; *see also Biolitec*, 604 F.Supp. 2d at 329; *U.S. ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F. Supp. 2d 35, 39 (D. Mass. 2000). Courts look at many of the same factors listed above to determine if fraudulent intent is present, but most often focus on whether the subsidiary is inadequately capitalized,

reflecting a “shoestring operation.” *163 Pleasant St.*, 960 F.2d at 1094. By contrast, when a parent invests money when necessary in order to maintain or improve the subsidiary’s business, drawing an inference of fraudulent intent “defies logic.” *Id.* Moreover, there is an important difference between a parent using the subsidiary’s corporate form as a fraud, and the parent and/or subsidiary committing a fraud.

[F]or purposes of piercing a corporate veil, defrauding the federal government as alleged is not the same as defrauding a corporation’s shareholders, and only the latter is sanctionable through the piercing of a corporate veil. ‘The difference between being a fraud and conducting one is important. Even a fully-capitalized, Fortune 500 corporation can embark on a fraud, but that would not make its corporate form a sham or its shareholders personally liable.’

U.S. ex rel. Siewick v. Jamieson Science and Eng’g, 191 F. Supp. 2d 17, 22 (D.D.C. 2002) (refusing to pierce corporate veil in FCA claim where corporation was an intact, separate, going concern at all times, and no fraudulent intent was shown), *aff’d U.S. ex rel. Siewick v. Jamieson Science and Eng’g*, 322 F.3d 738 (D.C. Cir. 2003).

In this case, the Government has never even alleged that either BIC or BIPI formed or otherwise used the corporate organization of Roxane for an improper purpose. While the Government claims that Roxane committed a fraud by reporting false prices, as the court in *Jamieson* explained, there is an important distinction between being a fraud, and conducting a fraud. *See Jamieson*, 191 F. Supp. 2d at 22; *aff’d Jamieson*, 322 F.3d at 741. Here, the Government does not have a shred of evidence that BIC or BIPI fraudulently created or used Roxane as a sham corporation to accomplish some misdeed. Indeed, the facts demonstrate quite the opposite, especially since Roxane was a stand-alone company in the pharmaceutical industry for decades before it became affiliated with BIC or BIPI. And even after it became a BIC subsidiary, based on all the facts discussed above, it would “defy logic” to infer that Roxane was

considered a “shoestring” operation by its corporate parent.⁵ See *163 Pleasant St.*, 960 F.2d at 1094. Court can grant summary judgment on this basis alone.

III. THERE IS NO VIABLE DIRECT LIABILITY CLAIM AGAINST BIC OR BIPI.

Faced with the lack of evidence to support its alter ego claim, the Government recently changed tactics and for the first time, in a motion to compel filed after the close of discovery, contended that BIC and BIPI should be held directly liable under the False Claims Act (“FCA”). (See 2/13/09 Memorandum in Support of Plaintiffs’ Motion to Compel Testimony at pp. 6-9) This theory of liability cannot be found anywhere in the Government’s initial complaint or in its First Amended Complaint, filed just last December. Plaintiffs’ last-ditch effort to keep BIC and BIPI in this case fails, as there is no legal or factual support for holding BIC or BIPI independently liable for Roxane’s alleged conduct.⁶

A. Plaintiffs’ FCA Claims Fail As A Matter Of Law Because There Is No Evidence Showing Causation or Knowledge.

Because there are no FCA allegations in the Complaint against BIC or BIPI, the Government’s theory of liability is not clear; however, the facts plainly demonstrate that the Government cannot succeed under any theory. Causation under either § 3729(a)(1) or

⁵ Although it is unnecessary to even reach the third prong of the test, plaintiffs cannot show that failure to pierce the corporate veil in this case will lead to injustice. *163 Pleasant St.*, 960 F.2d at 1092-93. Even if Roxane is unable to fully satisfy a judgment (a fact plaintiffs have never alleged) it does not mean that Plaintiffs will suffer injustice. *Janieson*, 191 F. Supp. at 22, fn. 5 (where a defendant’s inability to satisfy judgment is not “the result of undercapitalization or other fraud. . . potential inability to execute a monetary judgment against the corporation is created by the underlying, time-honored purpose of the law limiting liability by incorporation, rather than an inequity”); see also *Kneepkins*, 115 F. Supp. at 40 (no unfairness or inequity where parent did not strip subsidiary of assets “dreading a future day of reckoning in this case”). Plaintiffs’ preference for a deeper-pocket to support their oversized damages claim does not require piercing Roxane’s corporate veil.

⁶ Indeed, this Court need not even consider the Government’s newfound theory as it is too late to raise a new theory of liability that was not articulated in its Complaint. See *Logiodice v. Trustees of Me. Cent. Inst.*, 170 F. Supp. 2d 16, 30-31 n.12 (D. Me. 2001), aff’d, 296 F.3d 22 (1st Cir. 2002) (declining to consider “theory of liability . . . not detectable in the Complaint”; observing, “[p]laintiffs are not entitled to raise a new theory of liability for the first time in opposition to a motion for summary judgment”); *Bogdahn v. Hamilton Standard*, 973 F.Supp. 52, 53-54 (D. Mass. 1997) (criticizing plaintiff’s summary judgment strategy of “refram[ing] the causes of action in the hope of latching on to something that would work”).

§ 3729(a)(2) of the FCA requires the defendant to take an affirmative act. *See U.S. v. Pres. & Fellows of Harvard College*, 323 F. Supp. 2d 151, 186, 189 (D. Mass. 2004) (although defendant contributed to the “falsity” of claims, defendant could not be liable because he did not act to submit claims); *see also U.S. ex rel. Bartlett v. Tyrone Hosp., Inc.*, 234 F.R.D. 113, 126 (W.D. Pa. 2006) “[M]ere knowledge of the submission of claims and knowledge of the falsity of those claims is insufficient to establish ‘causation’ under the FCA.” *Harvard College*, 323 F. Supp. 2d at 186; *see also Bartlett*, 234 F.R.D. at 126 (dismissing defendants where plaintiffs only alleged knowledge of false records, but not action to cause their creation). Indeed, “[b]eing a parent corporation of a subsidiary that commits a FCA violation, without some degree of participation by the parent in the claims process, is not enough to support a claim against the parent for the subsidiary’s FCA violation.” *U.S. ex rel. Tillson v. Lockheed Martin Energy Sys.*, No. 5:00CV-39-M, 5:99CV-170-M, 2004 WL 2403114, *33 (W.D. Ky. Sept. 30, 2004).

In addition to an affirmative act, the Government must also show that BIC and BIPI possessed the requisite scienter. Under § 3729(a)(1), a defendant must know both that the claims were false *and* that they were being submitted. Under § 3729(a)(2), a defendant has to know that records were false and have acted with the *purpose* of getting a false claim paid. *See Harvard College*, 323 F. Supp. 2d at 188; *Allison Engine Co., v. U.S. ex rel. Sanders*, 128 S. Ct. 2123, 2130 (U.S. 2008); *U.S. ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 46 (D. Mass. 2009). Thus, at a minimum, to hold BIC or BIPI independently liable under Plaintiffs’ theory of the FCA, Plaintiffs must show that BIC and BIPI were actively involved in setting *and* publishing AWPs and WACs *for each of the nine Roxane drugs at issue*, knew the Government used Roxane’s published prices for reimbursement of Roxane’s drugs and took part in actively marketing the drugs at issue. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 478 F.

Supp. 2d 164, 175 (D. Mass. 2007); *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 12, 15 (D. Mass. 2007). There is no evidence to support this.

B. Neither BIC Nor BIPI Took Action To Cause False Claims To Be Submitted Or False Records To Be Created.

The undisputed facts in this case simply do not support a claim that BIC or BIPI knowingly participated in the submission of false claims for any of the Roxane drugs at issue. As this Court has repeatedly held, this analysis must be done on a drug-by-drug basis. *See Mass. v. Mylan Labs., et al.*, 608 F.Supp. 2d 127, 144, 154-55 (D. Mass. 2008).

1. There is no evidence that BIC had any involvement in setting or reporting AWPs for Roxane products.

BIC is a holding company that has no active business of its own. (56.1 ¶¶ 2-3) The record is devoid of any evidence that BIC had any direct involvement in either setting the AWPs or WACs for any subject drugs or reporting Roxane AWPs or WACs to the pricing compendia. Moreover, there is no evidence that BIC ever marketed the Roxane drugs in any way, much less that it “marketed the spread.” In a desperate attempt to link BIC to Roxane’s pricing decisions, plaintiffs have raised documents that indicate that Mr. Russillo *may* have consulted with Werner Gerstenberg regarding *one* price change for *one* drug at issue – a furosemide price change in 2000. (56.1 ¶¶ 70-71) Even if Mr. Gerstenberg was consulted regarding this one price change, plaintiffs entirely ignore the fact that Mr. Gerstenberg served as President of both BIC *and* Roxane during this time period, and Mr. Russillo’s undisputed testimony is that Mr. Gerstenberg “would have been acting as President of Roxane” in that situation. (56.1 ¶¶ 30, 71) Thus, Mr. Gerstenberg’s potential involvement proves nothing with regard to BIC.

2. There is no evidence that BIPI had any involvement in setting or reporting AWPs for Roxane's generic drugs.

Plaintiffs have no evidence that BIPI had any involvement in setting, approving or reporting AWPs or WACs for any of the multisource products at issue that account for the vast majority of the Government's damages claim. Nor is there any evidence that BIPI was directly involved in marketing Roxane's multisource products. This is certainly the case for ipratropium bromide. Roxane set and reported the AWP and WAC prices for the generic version of ipratropium bromide when it launched in 1996, and since the AWP for the product never changed, no one from BIPI could have been involved in making or reporting any changes. (56.1 ¶¶ 67-68) Nor is there an iota of evidence that anyone connected to BIPI had anything to do with the marketing of ipratropium bromide following its launch. Similarly, there is no such evidence with regard to Roxane's other multisource drugs. Accordingly, BIPI cannot be held liable for damages stemming from reimbursement claims for Roxane's ipratropium bromide, or any other multisource drugs at issue.

3. Plaintiffs' "evidence" with respect to Roxane's few branded generic drugs is insufficient to establish direct liability for BIPI.

The only purported "evidence" that Plaintiffs muster in an attempt to establish direct liability for BIPI are a few out-of-context facts that show limited involvement by specific BIPI employees related to the few Roxane drug products that had a natural synergy with BIPI's branded portfolio and expertise. These facts – namely, that several BIPI employees were in the sales and marketing chain of command for Roxane's branded generic products in the late 1998-2001 timeframe and may have approved certain pricing proposals – prove nothing with regard to the corporate entity of BIPI.

First, the undisputed evidence is that at all times, including the limited time when BIPI employees had oversight roles, Roxane employees maintained responsibility for the day-to-day

sales and marketing functions for its brand/branded generic products. (56.1 ¶¶ 75-79) There is no evidence that the BIPI employees set or reported the AWPs or WACs for those products. Nor is there evidence that they actively promoted or marketed Roxane's branded generic products. Any consultation with BIPI employees was for "approval" only and Plaintiffs have not pointed to any instance where BIPI personnel rejected or changed a price set by Roxane's marketing group.

Moreover, to the extent these employees had any direct involvement in approving or reviewing certain pricing decisions, they were acting on behalf of Roxane, as agents of Roxane and in Roxane's interests. (56.1 ¶¶ 90-94) It is a well-established that employees with roles at two affiliated companies "can and do 'change hats' to represent the two corporations separately, despite their common ownership." *Bestfoods*, 524 U.S. at 68-69. Therefore, courts generally presume that when an employee with dual roles acts for the subsidiary, he is wearing his subsidiary hat and, as such, his actions cannot be imputed to the parent. *Id.* To overcome that presumption, there must be evidence showing that the employee was, in fact, acting on behalf of the parent. *Id.* at 70. (noting the presumption "wanes" as the actions become "plainly contrary to the interests of the subsidiary yet nonetheless advantageous to the parent"). Absent such a showing, the parent cannot be held liable for the individual's acts in his role for the subsidiary.⁷

See Raytheon Constructors Inc. v. Asarco Inc., 368 F.3d 1214, 1218-20 (10th Cir. 2003) (holding that no facts rebutted the *Bestfoods* presumption that defendant wore separate hats at corporation and minority shareholder and therefore his individual actions could not be imputed to the minority shareholder company); *see also Am. Med. Sys. v. Biolitec, Inc.*, 604 F.Supp. 2d 325, 330

⁷ While few cases address the situation where plaintiffs seek to hold a corporation liable for the acts of a sister corporation, not a parent, those that have indicate that the same legal principles and presumptions apply in the analysis. If anything, the burden on plaintiffs may be higher given the lack of ownership interest by the sister corporation. *See Nichols v. Pabtex, Inc.*, 151 F. Supp.2d 772, 780 (E.D. Texas 2001) (applying Texas law, but stating "the distinction between parent-subsidiary and sister-sister is not relevant."); *Dickson Marine, Inc. v. Panalpina, Inc.*, 179 F.3d 331, 338-39 (5th Cir. 1999) (noting it could be argued that a stronger showing is required for a sibling relationship).

(D. Mass. 2009) (holding plaintiffs failed to overcome presumption that defendants were acting in their roles at subsidiary company rather than parent company when involved in subsidiary's business).

As Professor Macey concluded, any role played by BIPI managers related to Roxane drugs was done while they were wearing their "Roxane hat" and benefited Roxane, not BIPI. There was no conflict in their duties and it was easy to distinguish on whose behalf the employee was working since BIPI and Roxane had distinct products. (56.1 ¶¶ 93-94) Because plaintiffs have no evidence to overcome the presumption that these managers were acting in their Roxane roles, Roxane, not BIPI, is responsible for any actions they took related to pricing or marketing of Roxane products.⁸

⁸ Any direct unjust enrichment claim Plaintiffs asserts fails for the same reasons. Plaintiffs have no evidence that BIC or BIPI were enriched in some way, let alone that it was unjust. Given the undisputed facts, neither BIC nor BIPI violated federal or state law or profited from it.

CONCLUSION

For the foregoing reasons, summary judgment should be granted in BIC's and BIPI's favor on all claims.

Dated: June 26, 2009

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on June 26, 2009, a copy to LexisNexis File and Serve for posting and notification to all parties.

By: /s/ Eric T. Gortner
Eric. T. Gortner